

# RBRVS: Still good news for physicians

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*Lately, many physicians have been saying they've become disillusioned with the RBRVS. They don't believe the physician payment reform will bring gains for their undervalued evaluation and management services. They don't trust the federal government to live up to its end of the bargain. However, no one should write off the RBRVS. As can be seen from the text below, RBRVS will protect undervalued evaluation and management services in an era of Medicare budget-cutting; it will introduce fairness and rationality into the Medicare payment system; it will provide a basis for arguing against unfair cuts in reimbursement (such as the recent ban on payment for most EKG interpretations) and it will bring the profession together to fight against any further cuts in the Medicare program.*

When the Resource-Based Relative Value Scale first came onto the health policy scene, physicians supported it because it would introduce fairness and rationality into the Medicare payment system, unite the medical profession, and, most of all, because it would be good for patients. But lately, I've been hearing many of my colleagues say they've become disillusioned with the RBRVS's implementation — they don't trust the federal government to live up to its end of the bargain.

Well, I don't trust the federal government to live up to its bargain, either — at least not without concentrated pressure on it to do so. However, I don't think the medical profession should write off the RBRVS. Despite many problems — some immediate and some potential — it still will do what it was intended to do.

For instance, under the RBRVS, relative values are expected to increase substantially for most evaluation and management (E/M) services. Skeptics have suggested that the RBRVS will be used only to cut surgical values — and fees. New estimates show, however, that the RBRVS will increase relative values for E/M services by 30% on average, and that, as a result, Medicare payments for these services will increase substantially above 1991 payments under a "budget neutral" RBRVS fee schedule.

Better yet, the RBRVS protects undervalued evaluation and management services provided by all physicians *even when the budget is cut*. Consider what would happen to a \$30 office visit from 1991 to 1996 in a purely hypothetical scenario in

which fees normally would have been given a 15% inflation increase, but Congress cuts payments 10% below inflation. In 1996, that same office visit fee would total \$31.05 without the RBRVS. With the protected 30% gain for E/M services expected under the RBRVS, it would total \$40.36. Especially in this budget-cutting climate, the RBRVS will protect fees for the E/M services *all* physicians provide.

Exactly what effect there will be on an individual's practice depends on several factors, however. Because of elimination of geographic differentials and limits on balance billing, for some there will be no actual gain (or even a reduction) for E/M services. Where physicians practice, how often they accept assignment, how much they charge in excess of Medicare's "approved amount" for unassigned claims, and their mix of services, will determine the effect on their practices. *But regardless of each individual's gain or loss, the RBRVS will enhance payments overall for physicians' E/M services compared with what would have been.*

Another benefit is that the RBRVS allows physicians to unite for a fair conversion factor and to oppose further cuts in the Medicare program, rather than engaging in internal squabbling. The conversion factor that makes the RBRVS into a real fee schedule applies to *all* physician services. That means the entire profession has a stake in making sure it's fair and an incentive to work *together* to stave off future Medicare cuts. In fact, every medical group that testified before the Physician Payment Review Commission (PPRC) last December, including the American Medical Association, the American Society of Internal Medicine, the American Academy of Family Physicians and the American College of Surgeons, opposed HCFA's proposal to lower the conversion factor. HCFA has indicated it will assume volume will increase and that it will set the conversion factor lower to make up for that assumed increase.

The RBRVS also provides a basis for opposing unfair cuts in specific procedures. For example, the profession can argue that the ban on reimbursement for most EKG interpretation is contrary to the RBRVS, because the study said the service indeed has a value. The influential PPRC agrees, giving the profession a real opportunity to get this cut reversed. Without the RBRVS, it would have been far more difficult to make that case.

Continued support for the RBRVS allows the profession to be *for* — not just against — something. If it wasn't for the medical profession's support for the RBRVS, we'd all be

This article was submitted to the *Journal* by Dr Boyle, president of ASIM, through John H. Houk MD, President of the Hawaii Society of Internal Medicine.

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## AXID® (nizatidine capsules)

**Brief Summary:** Consult the package insert for complete prescribing information.  
**Indications and Usage:** 1. Active duodenal ulcer—for up to 8 weeks of treatment. Most patients heal within 4 weeks.

2. Maintenance therapy—for healed duodenal ulcer patients at a reduced dosage of 150 mg h.s. The consequences of therapy with Axid for longer than 1 year are not known.

**Contraindications:** Known hypersensitivity to the drug. Because cross sensitivity in this class of compounds has been observed, H<sub>2</sub>-receptor antagonists, including Axid, should not be administered to patients with a history of hypersensitivity to other H<sub>2</sub>-receptor antagonists.

**Precautions:** General—1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Dosage should be reduced in patients with moderate to severe renal insufficiency.  
3. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

**Laboratory Tests:** False-positive tests for urobilinogen with Multistix® may occur during therapy.

**Drug Interactions:** No interactions have been observed with theophylline, chlordiazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450 enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increased serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** A 2-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a 2-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a 2-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

**Pregnancy—Teratogenic Effects—Pregnancy Category C**—Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in 1 fetus, and at 50 mg/kg, it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in 1 fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Studies in lactating women have shown that 0.1% of an oral dose is secreted in human milk in proportion to plasma concentrations. Because of growth depression in pups reared by treated lactating rats, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

**Pediatric Use:** Safety and effectiveness in children have not been established.

**Use in Elderly Patients:** Healing rates in elderly patients were similar to those in younger age groups as were the rates of adverse events and laboratory test abnormalities. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

**Adverse Reactions:** Clinical trials of varying durations included almost 5,000 patients. Among the more common adverse events in domestic placebo-controlled trials of over 1,900 nizatidine patients and over 1,300 on placebo, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common with nizatidine. It was not possible to determine whether a variety of less common events were due to the drug.

**Hepatic:** Hepatocellular injury (elevated liver enzyme tests or alkaline phosphatase) possibly or probably related to nizatidine occurred in some patients. In some cases, there was marked elevation (>500 IU/L) in SGOT or SGPT and, in a single instance, SGPT was >2,000 IU/L. The incidence of elevated liver enzymes overall and elevations of up to 3 times the upper limit of normal, however, did not significantly differ from that in placebo patients. All abnormalities were reversible after discontinuation of Axid. Since market introduction, hepatitis and jaundice have been reported. Rare cases of cholestatic or mixed hepatocellular and cholestatic injury with jaundice have been reported with reversal of the abnormalities after discontinuation of Axid.

**Cardiovascular:** In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in 2 individuals administered Axid and in 3 untreated subjects.

**CNS:** Rare cases of reversible mental confusion have been reported.

**Endocrine:** Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to nizatidine. Impotence and decreased libido were reported with equal frequency by patients on nizatidine and those on placebo. Gynecomastia has been reported rarely.

**Hematologic:** Fatal thrombocytopenia was reported in a patient treated with nizatidine and another H<sub>2</sub>-receptor antagonist. This patient had previously experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

**Integumental:** Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

**Hypersensitivity:** As with other H<sub>2</sub>-receptor antagonists, rare cases of anaphylaxis following nizatidine administration have been reported. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

**Other:** Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine have been reported.

**Overdosage:** Overdoses of Axid have been reported rarely. If overdosage occurs, activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis does not substantially increase clearance of nizatidine due to its large volume of distribution.

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Additional information available to the profession on request.



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## ALCOHOL (Continued from page 285)

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worse off. No one can say that change won't be coming. Those who don't like the RBRVS and the limits on balance billing should consider the alternatives: mandatory assignment, MD-DRGs, and fees set by the government without any professional input. The RBRVS gives the profession a voice, and it enables us to ward off more objectionable measures.

Finally and most importantly, *the RBRVS is good for our patients*. It will increase the emphasis on preventive care and on evaluating and managing their treatment, and decrease the emphasis on costly high-tech services. It also will help improve access to care in underserved rural areas.

So you see, to paraphrase Mark Twain, reports of the death of the RBRVS are greatly exaggerated. But medicine can't rely on trust that everything will turn out okay. We must fight to preserve the promise of physician payment reform.

That means opposing policies that will undermine the RBRVS (such as a behavioral assumption that would lower the fee schedule conversion factor). It means working to change policies — such as the ban on reimbursement for EKG interpretation — that give with one hand and take away with the other. And it means supporting further changes that will make the system even better.

The RBRVS unites physicians under one fair and rational payment system to fight future detrimental budget cuts in Medicare. Lawmakers faced with a divided house of medicine easily can use that division to cut Medicare payments even further. But if they're faced with a profession that's united under the RBRVS, it won't be easy.

Support for the RBRVS has been right — for our profession and for our patients. The RBRVS will protect undervalued evaluation and management services in an era of Medicare budget cutting, increase access and the emphasis on preventive care for patients, and introduce fairness into the Medicare payment system. *But we must fight together — as a profession — to make sure it is implemented in the way Congress intended.*